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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,724	11/13/2000	Clifford Tabin	HMSU-P14-006	7675
28120	7590	05/13/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			HOWARD, ZACHARY C	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SUPPLEMENTAL

Notice of Allowability

Application No.

09/711,724

Examiner

Zachary C. Howard

Applicant(s)

TABIN ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/16/2005.
2. ☒ The allowed claim(s) is/are 1,3,7,17,27,29,30,32,34-36,42-44,47-49,63,66-69,78,92 and 94-98.
3. ☒ The drawings filed on 13 November 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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SUPPLEMENTAL EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Halstead on 5/6/2005.

The application has been amended as follows:

In claim 78, replace the entire text of the claim with the following text:

78. An assay for identifying compounds that antagonize the hedgehog pathway, comprising:

- (a) providing a cell expressing a naturally occurring *patched* protein, which cell transduces intracellular signals of the hedgehog pathway and wherein said *patched* protein binds a naturally occurring *hedgehog* protein;
- (b) contacting the cell with a test compound;
- (c) detecting a change in the level of activation of the *hedgehog* pathway in said cell in the presence of said test compound by detecting a change in *GLI* or *GLI3* expression in the cell, in which *GLI* or *GLI3* expression is responsive to the hedgehog pathway,

wherein a decrease in the expression of the *GLI* gene in the cell or an increase in the expression of the *GLI3* gene in the cell in the presence of said test compound in comparison to the absence of said test compound is indicative of a decrease in the level of activation of the hedgehog pathway, and thus is indicative of a compound that antagonizes the hedgehog pathway.

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Add new claim 98:

98. An assay for identifying compounds that antagonize the hedgehog pathway, comprising:

- (a) providing a cell expressing a naturally occurring *patched* protein, which cell transduces intracellular signals of the hedgehog pathway and wherein said patched protein binds a naturally occurring *hedgehog* protein;
- (b) contacting the cell with a test compound;
- (c) detecting a change in the level of activation of the hedgehog pathway in said cell by detecting a decrease in the expression of the *GLI* gene in the cell or an increase in the expression of the *GLI3* gene in the cell in the presence of said test compound, in which *GLI* or *GLI3* expression is responsive to the hedgehog pathway,

wherein a decrease in the level of activation of the hedgehog pathway in the presence of said test compound in comparison to the absence of said test compound is indicative of a compound that antagonizes the hedgehog pathway.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER